



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

53913

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 20, 2003

Mr. Seiichi Nakada, President
Imperial Chef's Food, Inc.
926 East 4th Street
Los Angeles, CA 90013

W/L 28-03

Dear Mr. Nakada:

On January 21-24, 2003, we inspected your seafood processing facility, located in Los Angeles, California. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly your prepared meals in serving containers that contain cooked, ready-to-eat fishery products and/or fresh histamine-forming fishes such as Spanish Mackerel are adulterated, in that the meals have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov. Please note that the wholesale portion of your operations is subject to the seafood HACCP regulations.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(a), and (b). However, your firm does not have a HACCP plan for products such as fresh mackerel to control the hazard of histamine formation. In addition, your firm prepares cooked fish and fishery products including salmon and shrimp, and does not have a HACCP plan to control pathogen survival through cooking, or pathogen growth for these products.

2. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However your firm did not maintain any sanitation monitoring records required for the processing of your prepared lunch products that include seafood.
3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor one or more of the eight areas of sanitation with sufficient frequency to ensure control as evidenced by:
 - a. Failure to hold food under such condition to minimize the potential for growth of microorganisms or the contamination of food. For example, a refrigerator holding raw, precooked fishes including Spanish Mackerel was observed at 52 degrees Fahrenheit.
 - b. Failure to take necessary precautions to protect against contamination of food and food contact surfaces as evidenced by:
 - The aprons worn by employees preparing and packaging food were observed dirty with remnant dirt and debris.
 - Three employees were observed wearing their food preparation aprons while handling trash and while on breaks outside the preparation area.
 - An apron was observed stored on a railing next to the toilet in the ladies bathroom.
 - The blind covering the windows in different rooms were covered with dirt and grime. In particular, the blind in the assembly room (cooling area) was directly adjacent to uncovered, exposed cooked food waiting to be packaged.
 - A fan in the cooling area was observed covered with dirt and grime.
 - Two employees were observed wearing hair nets in an ineffective manner while handling processed food products. Another employee was observed wearing a baseball-style cap with exposed hair while processing food.
 - c. Failure to provide adequate screening or other protection against pests. For example, the window screen next to the cooling area was torn approximately 7x7 inches in the right bottom corner and the window was open during the time of the inspection, directly to the outside. Cooked food products were observed uncovered next to this window for cooling. In addition, two fly sticky strips with approximately 15 dead flies were observed hanging directly over the assembly working tables in the middle of the room.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to recommend that the United States bring a legal action to seize your product(s) and/or enjoin your firm from operating.

Letter to Mr. Seiichi Nakada
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Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and state when you will correct any remaining deviations.

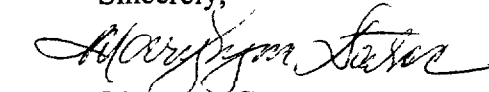
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your written reply should be directed to:

Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612-2445.

If you have questions regarding any issue in this letter, please contact Mr. Robert B. McNab, Compliance Officer at (949) 798-7709.

Sincerely,


for Alonza E. Cruse
District Director